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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,261	03/07/2001	David McElroy	950.044US1	5526

7590

06/05/2002

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
P.O. Box 2938  
Minneapolis, MN 55402

EXAMINER
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FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 06/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/801,261

Applicant(s)

McElroy et al

Examiner

FOX

Group Art Unit

1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -1- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 4/23/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-51 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claim(s) 1-51 are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

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The application should be reviewed for errors. Errors appear, for example, in claim 33, which lacks a period at the end.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 and 3-7, drawn to a method of making transgenic animals, classified in class 800, subclass 21, for example.
- II. Claims 2, 8-21, and 28-29, drawn to a method of altering a transgene insertion comprising crossing plants containing a transgene flanked by repeating DNA, classified in class 800, subclass 260, for example.
- III. Claims 22-27 and 30-51, drawn to an altered transgene and plants containing it, classified in class 800, subclass 278, for example.

The inventions are distinct, each from the other because:

Inventions I and each of II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. The invention of Group I requires transgenic animals and methods for making them, not required by Groups II or III. The inventions of Groups II and III require methods for transforming plant cells, methods for regenerating whole plants therefrom, and methods for crossing transformed plants, each not required by Group I.

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Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process. Plants containing deleted transgenes can be made by transforming the parent generation plants with viral vectors or *Agrobacterium*-derived vectors in which some of the transfer DNA functions, tumor genes (*Agrobacterium*) or viral DNA has been deleted, as evidenced by the early work in this field. Plants containing rearranged transgenes can be obtained by transforming a transposon-containing plant with a transgene, and then observing alterations in the transgene due to transposon insertion. Alternately, transgenic plants can subsequently be transformed with a transposon to induce rearrangements. Additionally, chemical or irradiation-mediated mutagenesis of transgenic plants will result in alteration of transgenes. Amplification of transgenes occurs spontaneously, due to increased copy number of the inserted transgene inherent in some transformation techniques such as *Agrobacterium*-mediated transformation, wherein a single transgene on the Ti-plasmid vector may be introduced into multiple sites in the plant genome. Finally, the isolated "altered" transgene itself, as claimed in claims 40-51, could be obtained by any of the above methods. In addition, the mere recitation of "altered" in the transgene claims does not distinguish these claims from claims drawn to any transgene, since any transgene can be considered to be "altered" with respect to any other transgene of a slightly different sequence.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, fields of search, and classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 1, 2002

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180 1638

*David T. Fox* 114